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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,650	09/29/2000	Ursula Busse	1619.0080001/SRL/TBB	1706
26111 7590 08/22/2007 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER YU, MISOOK	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/675,650

Applicant(s)

BUSSE ET AL.

Examiner

MISOOK YU

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6, 9-11, 24, 26 and 35-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4, 6, 9, 24, 26 and 37-48 is/are allowed.
- 6) ☒ Claim(s) 5, 10, 11, 35, 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: sequence alignment (Exhibit A)

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/08/2007 has been entered.

Claims 4-6, 9-11, 24, 26, and 35-48 are pending and examined on merits. This Office action contains new grounds of rejection. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 6 and 9 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment.

The Following Are the New Grounds of Rejection

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 as currently constructed depends on claim 4. The property boundary of a dependent claim should be within the property boundary set by the base claim. However, claim 5 as currently

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constructed is outside of the property boundary in claim 4. In other words, an isolated nucleic acid encoding SEQ ID NO: 3 does not comprises SEQ ID NO: 1. Note the art rejection of claim 5 below.

Allowable Subject Matter

The indicated allowability of claims 5, 10, 11, 35, and 36 is withdrawn in view of the following rejection based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 11, 35, and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This written description is made due to the limitation "a promoter" in claims 10 and 35.

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a function (i.e. a promoter effective to initiate transcription). There is not even identification of any particular portion of the structure that must be conserved in order to have the recited function. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

The limitation "a promoter" encompasses a native promoter that controls the expression of SEQ ID NO: 1 that is not further described. DD3 (PCA3) promoter had not been known at the time the instant application was filed. In fact, it was not isolated until Verhaegh et al., (J. Biol. Chem. Vol. 275, pages 37496-37503).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by US Pat 6,465,611 (the '611 patent hereinafter, filling date of January 15, 1999), or US Pat 6,395,278 (the '278 patent hereinafter, filling date of July 13, 1999).

Claim 5 is drawn to an isolated nucleic acid encoding SEQ ID NO: 3. Either the '611 patent or the '278 patent teaches an isolated nucleic acid encoding SEQ ID NO: 3. Note the attached sequence alignment (Exhibit A).

Allowable Subject Matter

Claims 4, 6, 9, 24, 26, and 37-48 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU
Primary Examiner
Art Unit 1642

/Misook Yu/

Alignment Scores:			
Pred. No.:	7.09e-12	Length:	718
Score:	123.00	Matches:	23
Percent Similarity:	100.00%	Conservative:	0
Best Local Similarity:	100.00%	Mismatches:	0
Query Match:	100.00%	Indels:	0
DB:	3	Gaps:	0

```

Qy      1 MetPheLeuHisileSerSerProPheLysTyrProHisThrGlnGluAlaGlnLysGlu 20
      |||||
Db      189 ATGTTTTTGCACATTTCCAGCCCTTTTAAATATCCACACACACAGGAAGCACAAAAGGAA 248
      |||||
Qy      21 AlaGlnArg 23
      |||||
Db      249 GCACAGAGA 257

```

http://es/ScoreAccessWeb/GetItem.action?AppId=09675650&seqId=09323... 8/8/2007

Exhibit A

```

; LENGTH: 718
; TYPE: DNA
; ORGANISM: Homo sapien
; FEATURE:
; NAME/KEY: misc_feature
; LOCATION: (1)...(718)
; OTHER INFORMATION: n = A,T,C or G
US-09-232-149A-313

```

Alignment Scores:

Pred. No.:	7.09e-12	Length:	718
Score:	123.00	Matches:	23
Percent Similarity:	100.00%	Conservative:	0
Best Local Similarity:	100.00%	Mismatches:	0
Query Match:	100.00%	Indels:	0
DB:	3	Gaps:	0

US-09-675-650-3 (1-23) x US-09-232-149A-313 (1-718)

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Qy      1 MetPheLeuHisIleSerSerProPheLysTyrProHisThrGlnGluAlaGlnLysGlu 20
          ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      189 ATGTTTTTGCACATTTCCAGCCCTTTTAAATATCCACACACACAGGAAGCACAAAAGGAA 248

Qy      21 AlaGlnArg 23
          ||||||||
Db      249 GCACAGAGA 257
<!--EndFragment-->

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